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| 09/582,524      | 06/27/00    | BURNE                | 0769.00140          |

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HM12/0314

| EXAMINER |
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| ART UNIT | PAPER NUMBER |

1641  
DATE MAILED:

03/14/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/582,524

Applicant(s)

BURNE ET AL.

Examiner

Terri L Ivory - McCaa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2000.
- 2a) ☐ This action is FINAL.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 82-150 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 82-150 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to because for the reasons set forth in the attached PTO 948 form. Correction is required.

### ***Specification***

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

### **Arrangement of the Specification**

3. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.
4. The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.

- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
  - 1. Field of the Invention.
  - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 82 – 150 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The term "relative" in claim 82,94 are a relative term which renders the claim indefinite. The term "relative" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear how the flow of reagents correspond with the substrate.

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8. Claim 105 recitation "first and second antibodies" lacks antecedent basis.
9. Claims 82, 97, 98, 104, 106, 109, 110, 111, 115, 121, 129, 132, 137, 140, 141, 142, 145, 146, the phrase "substantially" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 82-89, 90-96, 99, 100-103, 107, 146-149 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergman ( U.S. Patent 5,505,955) in view of May et al ( U.S. Patent 5,622,871).

Bergman teaches on a method for detecting the presence of autoantibodies in biological fluids such as serum ( Col.3, line 67). (a) providing an antigen specific for autoantibody such as thyroid peroxidase, (b) Providing a substrate having an immobilized antibody to antigen, (c) Contacting antigen with body fluid sample to allow binding of the complex, (d) mixture is allow to flow into test tube to contact with immobilized monoclonal antibody (e) providing labeling means such as labeled non

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immobilized mobile monoclonal antibody to allow binding to the complex, (f) indication of presence of autoantibody in sample of body fluid (Fig 1, Col.3 and Col.4).

Bergman further teaches on various methods for detection of autoantibodies. He states that the construction of sandwich complexes with specification of suitable properties for detection of certain autoantibodies can be tailored when both the immobilized and labeled antibodies are suitable monoclonal antibodies (Col. 4, line50-55). He teaches on three different competitive situations involving analyte antibody analysis as follows: Fig 1, analyte competes for same binding site as the immobilized antibody, Fig 2 analyte competes for the same binding site as the labeled antibody and (Fig 3) analyte competes for the same binding site as both labeled and immobilized antibodies.

Bergman does not teach on using the method of the invention on a test strip substrate.

May teaches on a test strip format in which assays involving specific binding or immunoassays may be formatted in a test strip to provide convenience for home or clinical use. In a procedure a sample may be applied to a portion of the test strip and allow to permeate through the test material (Col.1, Line 35-60). A control zone may be designed to detect unrelated signal to user that the device is working properly. The sample progresses to a detection zone where a specific binding partner for the sample analyte is immobilized. Analyte concentration may be determined by a labeled reagent which can be incorporated within the test strip or applied thereto. Direct labels such as metallic sols (eg. gold) can be used for an analytical result (Col.5,line29-32). The

substrate involved in the test strip are porous membranes such as nitrocellulose (Col.7, Line 5-10).

It would have been obvious to one of ordinary skill in the art to modify the method of Bergman by incorporating the method to a test strip device as taught by May because the use of test strip devices are intended for rapid analytical results with the least degree of skill and involvement from the user.

11. Claims 104-106, 108, 109-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergman in view of May as applied to claims 82-89, 90-96, 99, 100-103, 107, 146-149 above, and further in view of Janeway et al ( Immunobiology 3<sup>rd</sup> ed.)..

See discussion on Bergman set forth above. Although this reference does not specifically teach on the detection of two autoantibodies in a single assay, it is conventional in the art to extract crude thyroid peroxidase antigen, comprising specific epitopic sites for binding of specific autoantibodies. These components may be incorporated into an immunoassay format for the detection of specific analyte antibodies. Janeway et al teaches on multivalent antigens and antibody binding and also monoclonal antibody production(2:13& 2:17).

It would have been obvious to one of ordinary skill in the art to modify the method Bergman and May by providing a multivalent antigen and monoclonal antibodies specific for the pertinent epitopes as taught by Janeway because this assay method provides for a selective and sensitive assay for dual analyte detection.

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12. Claims 115-145<sup>4</sup>&150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergman in view of May as applied to claims 82-89,90-96,99,100-103,107,146-149 above, and further in view of Foster et al ( U.S.Patent 4444879).

See discussion on Bergman in view of May as set forth above. These references differ from the instant invention in failing to teach a kit.

Foster et al teaches on a an embodiment of a kit in which an immunoassay of the invention is incorporated. The kit contains, a substrate, buffers and other reagents, controls, instructions, containers and any other pertinent components of the immunoassay of the invention( Col. 15, Lines 12-34).

It would have been obvious to incorporate a kit for the method of Bergman and May that contains all the necessary reagents and supplies as taught by Foster et al because Kits are well known in the art and are recognized for their advantages of economy and convenience.

13. Claims 97&98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergman in view of May as applied to claims 82-89,90-96,99,100-103,107,146-149 above, and further in view of Bergmann et al ( WO 95/06258).

See discussion on Bergman in view of May set forth above. These references differ from the instant invention in failing to teach on mixing test reagents with sample before addition to substrate.

Bergmann et al teaches on mixing and incubating sample in an uncoated test tube with thyroid stimulating hormone receptor and a competitor before addition to

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monoclonal antibody bound substrate. Addition of labeled antibody is added and detection on complex is determined ( page 16,Line 39-40, Page 17 Line 1-3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Bergman and May by mixing sample with the pertinent assay binding components before addition to substrate as taught Bergmann et al because the incubation step before addition to substrate would allow for adequate binding of components before addition to substrate containing an immobilized component.

### **Conclusion**

14. All claims are not allowed.

15. References: David et al U.S.Patent 4486530; Delacroix et al U.S.Patent 5206177; Wolters et al U.S. Patent 4343896; Shih U.S.Patent 5,077,198; Zuk et al U.S.Patent 4281061; Tzeng et al WO 9222797; Preissner et al Clin. Chem 34/91794-1798 (1988).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terri L Ivory - McCaa whose telephone number is 703-605-1207. The examiner can normally be reached on M-F 8:30-4:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Terri Ivory-McCaa  
Patent Examiner  
Art Unit 1641  
January 16, 2001



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800/641

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